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Evaluation of Sound Therapy Tinnitus Treatments with Concurrent Counseling in Active Duty Military Personnel

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14. ABSTRACT
Since 2007, tinnitus has been the number one reported service-connected disability in the U.S. Armed Forces. Debilitating tinnitus can negatively affect Soldier deployability by providing obstacles for return to and/or fitness for duty. The goal of the current study was to evaluate novel treatments (sound therapy with associated counseling) of debilitating tinnitus by comparing the Neuromonics Oasis to an Apple iPod Touch pre-loaded with tinnitus apps. The degree and severity of tinnitus was measured pre and post treatment with the following measurement indices: 1) Tinnitus Reaction Questionnaire (TRQ), 2) Levels of awareness, 3) Levels of disturbance, 4) Broadband noise minimum masking levels, and 5) Loudness discomfort levels. Data from 35 active duty personnel were used in the statistical analysis. Results suggest that use of either device paired with counseling provides statistically significant intervention in the treatment of tinnitus when evaluating efficacy with the TRQ ($p < .001$).

15. SUBJECT TERMS
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Introduction

Approximately 16 million of the estimated 30 to 60 million Americans who experience tinnitus will seek medical attention for treatment (Formby and Scherer, 2013; Hearing Center of Excellence, 2013). The prevalence of tinnitus in all branches of the U.S. military is likely higher than that of the general population. Since 2007, tinnitus and hearing loss are respectively the number one and two service-connected disabilities in the U.S. Armed Forces (figure 1). By the end of fiscal year (FY) 2012, a total of 971,990 Veterans (6.3 percent of all conditions; 917,969 male and 38,204 female) were receiving compensation for tinnitus. Additionally 115,638 new cases of tinnitus (9.7 percent of total cases of tinnitus) were reported that same FY (Department of Veteran Affairs, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013). Congress reported in the Tinnitus Research and Treatment Act of 2013 that in 2012, the Department of Veterans Affairs paid $1.5 billion for tinnitus service-connected disabilities. The cost outlay to the U.S. taxpayer could sustain an estimated growth of up to $3 billion by 2017 (S. Rep. HR 113-247).

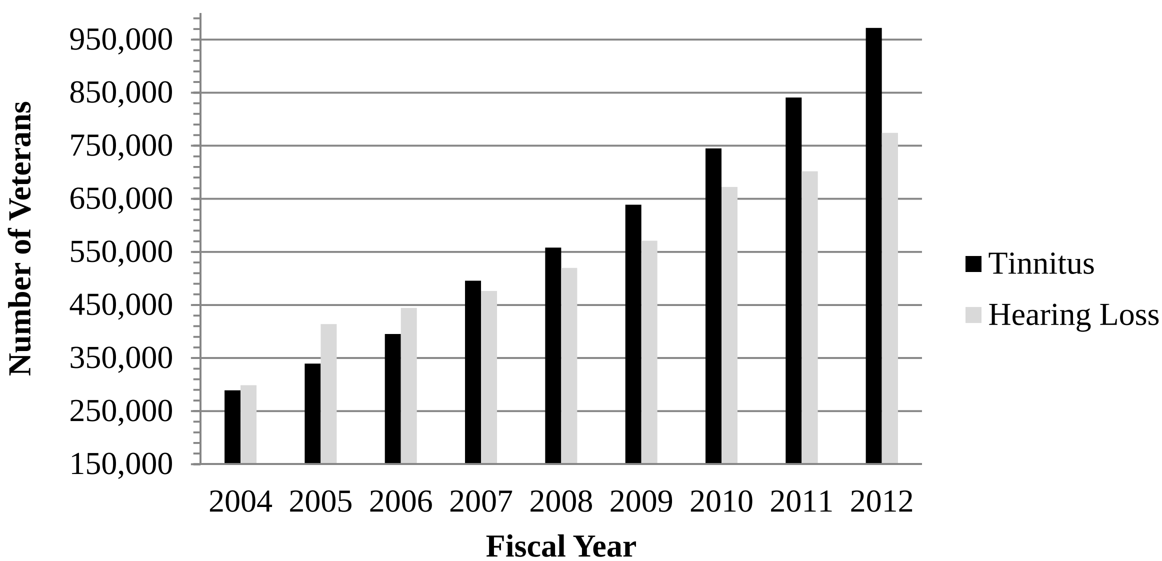

Figure 1. Prevalence of service-connected tinnitus and hearing loss by FY.

Background

Tinnitus is a symptom that is typically linked to hearing loss, acoustic trauma, exposure to medications (including but not limited to aminoglycosides and salicylates), head/neck injury, noise-exposure and/or blast-exposure. Further, tinnitus is often co-morbid with traumatic brain injury and post-traumatic stress disorder (Humes, Joellenbeck, and Durch, 2006). Tinnitus is the perception of sound in the absence of an acoustic signal, creating an environment that can provide "distracting, irrelevant and confusing auditory cues that compete with the real world acoustic cues relevant to the mission" (Yansakas, 2013). Tinnitus can also affect the emotional health, sleep, and concentration of the individual or Soldier (Humes et al., 2006).

Further, tinnitus is an individualized phenomenon varying in perception, duration, and severity. Noted perceptions of tinnitus include but are not limited to: ringing, buzzing, hissing,

humming, roaring, and/or whistling. Tinnitus can be either persistent or transient in nature, with persistent tinnitus defined as lasting five or more minutes either continuously or intermittently (Humes et al., 2006). The severity with which tinnitus is perceived and affects quality of life or health related quality of life (HRQoL) is not due to an increase in perceived magnitude or change in quality of the sound. Rather, it is likely tied more to the "psychological makeup, life experiences and current stress factors of the individual" (Humes et al., 2006).

Approximately one to two percent of individuals, or an estimated 2 million Americans, categorize their tinnitus to be distressing or debilitating, affecting HRQoL (Colucci, 2013; Formby and Scherer, 2013; Hearing Center of Excellence, 2013). This severe reaction in Soldiers could "lead to sleep disturbances and depression, factors that would negatively impact operational readiness" (Yansakas, 2013). Additionally, severe tinnitus not only could adversely affect the Soldier's HRQoL, but also his/her deployability and operational performance. The debilitating effects could also provide significant obstacles for return to duty and/or fitness for duty (Hill, Casto, and Nedostup, 2012). As of current print date, there is no known cure for tinnitus. There are however, a number of treatment options available to reduce the individual's perception of their tinnitus and its effect on HRQoL.

The main goal of treatment is to reduce or manage the symptoms associated with the experienced tinnitus. This is typically addressed with informational counseling (i.e. education), use of sound therapy, and/or psychological management (Newman and Sandridge, 2012). Sound therapy options include, but are not limited to use of sound generators (SG), maskers, amplification, and as a part of Tinnitus Retraining Therapy (TRT). Identifying the course of treatment or intervention is multifactorial. This decision is often driven by factors such as clinician knowledge and experience, patient characteristics and needs, health insurance coverage and/or benefit, and finally out-of-pocket expense to the patient. Davis, Paki and Hanley (2007) report a growing consensus in the treatment and management of tinnitus to provide a tandem approach of acoustic therapy paired with informational counseling. Further, Sweetow and Henderson Sabes (2010) state that tinnitus treatment options such as TRT, sound enrichment (i.e. amplification or sound generators) and acoustic desensitization (i.e. Neuromonics Tinnitus Treatment™) are all "successful in the majority of patients receiving them" (p.15). The goal of this study was to provide information and knowledge in identifying novel treatment options for debilitating tinnitus which may adversely affect Soldier deployability and operational performance.

Methods

Participants

Active-duty personnel (*N* = 40) were recruited and provided informed consent. A randomized, controlled trial between-subject design was used to assess the effectiveness of two tinnitus treatment options. Participants were required to be either a current Active Duty, Reserve, or National Guard service member aged 18 to 60 years old, or a Veteran who separated from service within the past 10 years, aged 19 to 60 years old. To be included in the study, participants were further required to meet the following criteria:

- A measured score of 17 or greater on the Tinnitus Reaction Questionnaire (TRQ);
- Measured audiometric thresholds equal to or less than 50 dB HL at 0.5, 1, 2, and 4 kHz with at least some usable hearing at higher frequencies;
- Cognitive, comprehension, and manual dexterity abilities that would allow for self-administration of treatment;
- Ability to attend all appointments;
- No complicating medical conditions (e.g. acute Meniere's disease);
- No significant clinically depressive nor anxiety disorders as determined by the initial pre-enrollment assessment of the Hospital Anxiety and Depression Scale (HADS);
- No drug and/or alcohol abuse that would prevent effective participation;
- No ongoing use of ototoxic medications;
- No pulsatile tinnitus (i.e., tinnitus that has a similar rhythm to that of the heartbeat and/or blood flow);
- Not subject to continued excessive noise exposure without effective hearing protection devices (HPD's);
- Motivated to seek treatment and with realistic expectations of treatment outcomes as determined at the initial pre-enrollment assessment; and
- Access to healthcare follow-up care for the 6-month-period of the study.

Materials

Participants in the experimental group (*n* = 30) received a customized (according to measured octave hearing thresholds) Neuromonics Oasis™ Device (figure 2a) with instructions for appropriate use which was to be used in concert with the Neuromonics Tinnitus Treatment Protocol™ (NTTP). The Neuromonics Oasis™ is a registered Class II medical device, which has been Food and Drug Administration (FDA)-cleared, patented and clinically tested (Neuromonics, Inc., 2014a, b). Participants in this group were asked to use the device for 2 to 4 hours each day for the duration of the study.

a) Neuromonics Oasis™ b) Apple iPod Touch™ c) Bang & Olufsen™ earphones

Figure 2. Devices used in the current study.

A control group consisted of participants (*n* = 10) who received a commercial-off-the-shelf (COTS) Apple iPod Touch™ (figure 2b) with the generic pre-downloaded tinnitus apps (figure 3): Tinnitus Masker™ (Explosive Apps, 2009) and Tinnitus Relief™ (LoL Software, 2010). Participants using this method were asked to select and use either of the two tinnitus apps for 2 to 4 hours each day for the duration of the study. Paired with this device, participants were

counselled according to the Tinnitus Retraining Therapy (TRT) Patient Counseling Guide (Henry, Trune, Robb and Jastreboff, 2007). All participants used Bang & Olfusen™ earphones with their assigned devices (figure 2c).

a) Tinnitus Relief™ b) Tinnitus Masker™

Figure 3. Tinnitus apps provided for use with the Apple iPod Touch™.

Dependent variables for both groups include: the Tinnitus Reaction Questionnaire (TRQ), measures of tinnitus awareness, tinnitus disturbance, broadband noise minimum masking levels (BBNMML), and loudness discomfort levels (LDL). Measures of each variable were taken at pre- and post-treatment intervals.

The primary measure of treatment efficacy used in this study was the TRQ (Wilson et al., 1991). The TRQ is a self-report survey designed to assess and measure psychological distress associated with the individual's experienced tinnitus (i.e., anxiety, anger, depression, etc.). Participants are asked to rate on a Likert scale from 'not at all' to 'almost all of the time' how their perceived tinnitus affected their quality of life and emotional state over the previous week. Scoring allows for a total possible scaled score of 0 to 104. Larger scores are equivalent to greater perceived distress.

Secondary measures of treatment efficacy utilized in the current study include both awareness and disturbance percentage levels. Awareness levels were measured by asking participants to rate on a scale of 0 to 100 percent, the amount of time the week prior to their appointment they were aware of their tinnitus. Disturbance levels were measured by asking participants to rate on a scale of 0 to 100 percent, the amount of time during waking hours that their perceived tinnitus was considered disturbing.

Procedure

All participants (N = 40) received identical audiometric evaluations, clinical surveys and appointment schedules. Due to military training and deployment schedules, treatment averaged 9.5 months with five on-site follow-up appointments in addition to an initial consult. Participants were randomly assigned to treatment groups, such that 30 participants received treatment with the Neuromonics Oasis™ device and 10 participants received the Apple iPod Touch™ pre-loaded with tinnitus apps.

Participation for both groups included an initial consult, five onsite follow-up appointments, and two courtesy phone calls (figure 4; Hill, Casto and Nedostup, 2012). At the initial consult,

participants provided informed consent and completed the HADS, full audiometric testing (including 10.0 and 12.5 kHz), tympanometry, BBNMMLs, LDLs, and the TRQ. All participants were counseled on what tinnitus constitutes and reviewed realistic expectations of benefit from study participation. The TRQ was subsequently administered within 1-week prior to the 2, 4, and 6 month on-site visit, with treatment efficacy measures comparing pre- (fitting) and post- (6 month) scores (Aksoy, Firat, and Alpar, 2007). Secondary efficacy measures (awareness and disturbance levels) in addition to BBNMML and LDLs were measured at the beginning (fitting appointment) and conclusion (final appointment) of participation in the study.

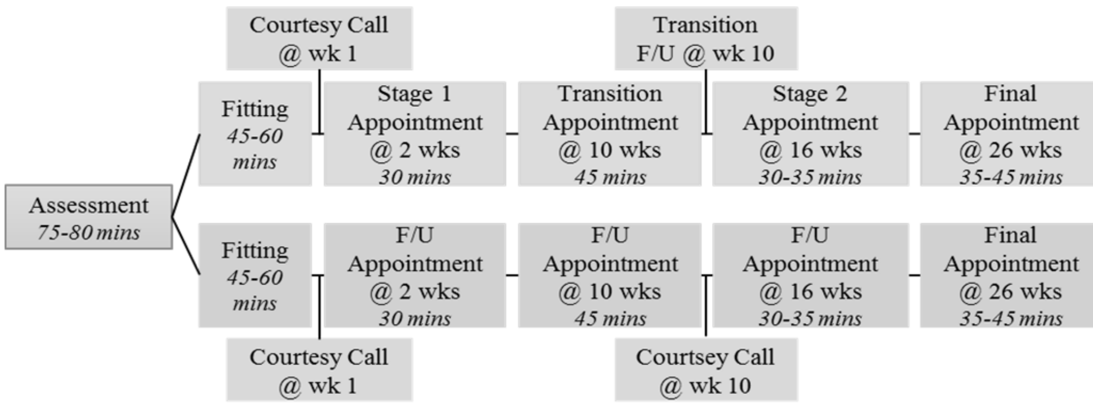

Figure 4. Chronology of appointments for participants in both treatment groups; Neuromonics Oasis^{TM} (top row), Apple iPod Touch^{TM} (bottom row).

At the conclusion of data collection, if the participant was identified as not receiving significant benefit from the assigned treatment protocol, he/she had the opportunity to switch to the untried treatment option. Significant benefit was defined as meeting the minimum threshold for clinical success observed with at least a 40 percent reduction in the TRQ score (Davis, Paki, and Hanley, 2007).

Results

Analysis of pre-treatment measures (TRQ, awareness, disturbance, BBN minimum masking, and loudness levels) between treatment groups was completed with a one way analysis of variance (ANOVA). This analysis failed to reveal a significant difference between treatment groups, indicating that although group sample sizes were small and unequal, the groups were not significantly different on ratings or scores on the TRQ. Similar findings were obtained on measured awareness, perceived disturbance, minimum masking and loudness levels.

Of the 40 participants in the current study, the data from 5 participants in the Neuromonics Oasis^{TM} group were excluded from final analysis due to loss to follow up (n = 3), medical withdrawal (n = 1), and an incomplete data set (n = 1). Of the total 35 participants whose data was used in the final analyses, only 25 completed LDL measures for the right and left ears at pre- and post- treatment (Neuromonics Oasis^{TM} n = 16, Apple iPod Touch^{TM} n = 9). Descriptive statistics for pre- and post-scores on test measures can be found in table 1.

Table 1
Mean and SD for pre- and post- measures.

	Neuromonics Oasis™		Apple iPod Touch™	
	Pre-	***Post-***	***Pre-***	***Post-***
	n = 25		*n = 10*	
TRQ (Raw)	39.1 (± 13.9)	16.2 (± 14.1)	37.5 (± 11.5)	7.8 (± 7.3)
TRQ (Percent)	39.0 (± 14.0)	15.7 (± 13.5)	36.0 (± 11.1)	7.7 (± 7.0)
Awareness	76.0 (± 24.5)	35.4 (± 27.7)	78.2 (± 22.4)	25.4 (± 24.9)
Disturbance	52.2 (± 23.5)	27.6 (± 28.9)	41.0 (± 19.9)	22.5 (± 30.5)
BBNMML	19.0 (± 10.7)	15.4 (± 12.6)	28.0 (± 16.9)	29.8 (± 19.8)
	n = 16		*n = 9*	
LDL right ear	78.4 (± 15.7)	84.3 (± 15.5)	78.5 (± 17.3)	84.1 (± 13.9)
LDL left ear	81.8 (± 12.6)	83.4 (± 14.1)	75.9 (± 16.1)	86.3 (± 10.6)

Note. Maximum score of the TRQ is 104; awareness and disturbance levels are reported percentages, with maximum score of 100; both BBNMML and LDL units of measure are dB.

A repeated-measures ANOVA for all 35 participants revealed a statistically significant main effect for time (i.e., pre- and post-treatment) independent of the device used on measures of the TRQ, awareness, and disturbance levels, $F = 21.60$, $p < .001$ (figures 5 and 6). A univariate analysis of the data revealed the following measures showed a statistically significant difference between pre- and post-treatment measures for all participants: the TRQ ($F = 74.01$, $p < .001$), awareness levels ($F = 48.62$, $p < .001$), and disturbance levels ($F = 10.56$, $p = .003$). Analysis of BBNMML measures failed to show statistical significance.

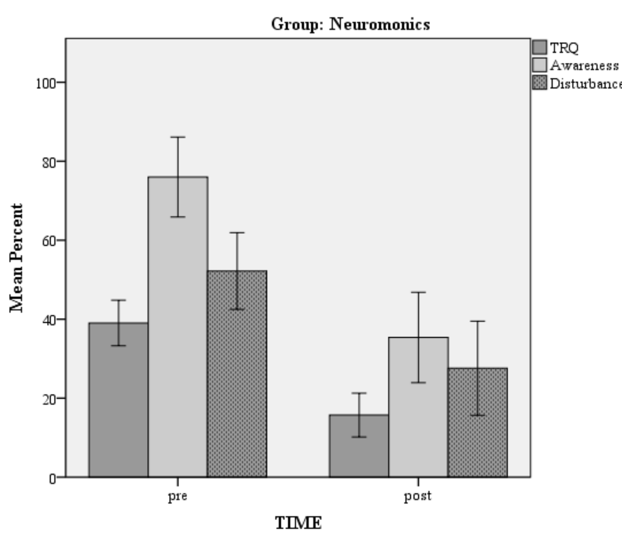

Figure 5. Effect of treatment for Neuromonic Oasis™ device users.

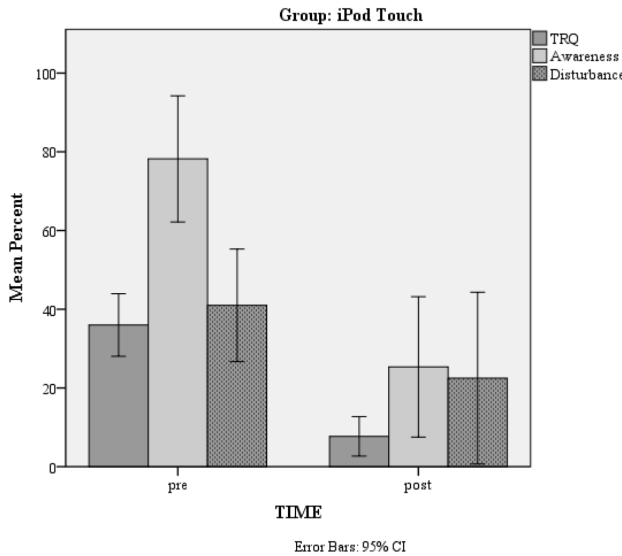

Figure 6. Effect of treatment for COTS Apple iPod Touch™ device users.

Though group or device used was not determined to be a significant main effect on measures of tinnitus in the current study, concern arose regarding possible variability in measures due to size differences between groups. Therefore, a repeated-measures ANOVA was completed for each group independently to determine the effect of treatment on each measure. Similar to the pooled data set, data from the Neuromonics Oasis™ device group revealed time to be a statistically significant factor ($F = 14.91$, $p < .001$). Specifically, pre- and post-measures of the TRQ ($F = 42.35$, $p < .001$), awareness ($F = 36.25$, $p < .001$), and disturbance ($F = 10.94$, $p = .003$) levels were all found to be statistically significant. Analysis failed to show statistical significance on measures of the BBNMML.

The analysis of data from those participants who used the COTS Apple iPod Touch™ with generic tinnitus apps also revealed a statistically significant effect of time ($F = 11.46$, $p = .006$). A univariate analysis of the test measures revealed statistically significant differences between pre- and post-measures of the TRQ ($F = 57.19$, $p < .001$) and awareness levels ($F = 16.71$, $p = .003$). For this treatment group, pre- and post- intervention measures of both disturbance levels and BBNMML measures failed to reach statistical significance.

Disturbance levels

The completed repeated-measures ANOVA on the pooled data set ($N = 35$) revealed a statistically significant difference in disturbance levels between pre- and post-measures ($p = .003$). Further, the tests of between-subjects effects failed to identify a significant difference between devices ($F = 1.28$, $p = .27$). However, analysis as completed with a repeated-measures ANOVA for each device group independently revealed disturbance levels were statistically significant between pre- and post-treatment measures for those who used the Neuromonics Oasis™ device ($F = 10.94$, $p = .003$) but not for the Apple iPod Touch™ users ($F = 3.73$, $p = .09$) (figure 7). Measured variability between pooled and independent group differences may be tied in part to group size differences.

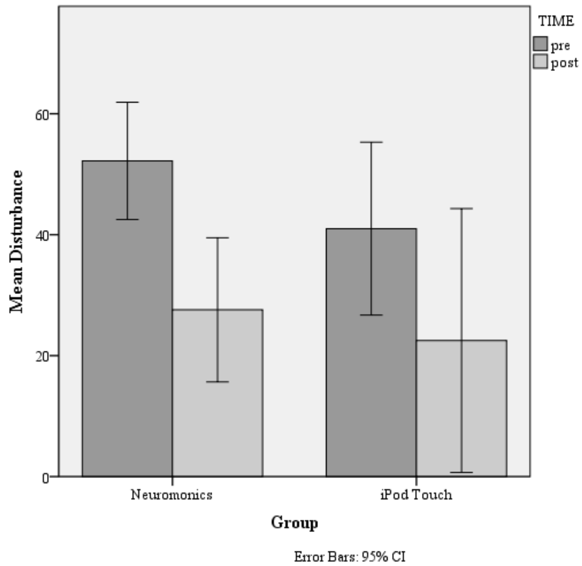

Figure 7. Mean disturbance levels for both groups pre- and post-treatment.

BBNMML and LDL

Analysis of BBNMML at pre- and post-treatment measures failed to reveal statistical significance for either treatment device. However, analysis of between-subject effects revealed a statistically significant difference between groups for post-treatment BBNMML measure scores (F = 6.46, p = .016). Participants in the Neuromonics Oasis^{TM} treatment group required a lower intensity of broad band noise (mean 15.4 dB) to effectively mask their tinnitus compared to that of the participants in the Apple iPod Touch^{TM} group (mean 29.8 dB) (figure 8).

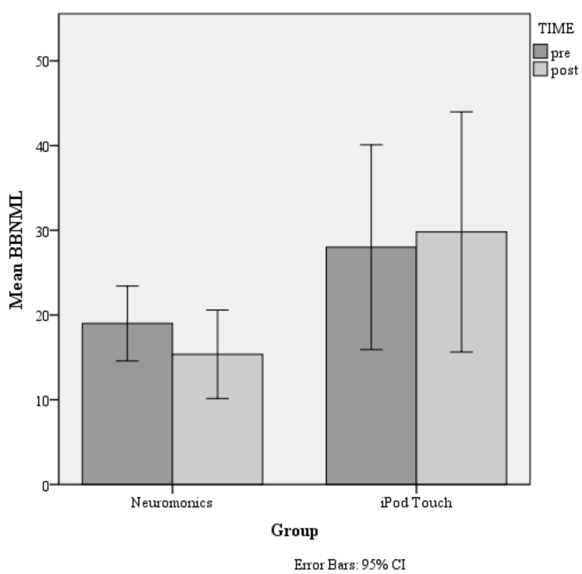

Figure 8. Mean BBNML for both groups pre- and post- treatment; measures are in dB.

Analysis as completed with a repeated-measures ANOVA for scores of the LDL right and left ears at pre- and post- treatment were completed for each device group independently. Both

analyses failed to reveal a statistically significant effect of time (i.e. use of treatment at pre- and post-intervention) for either device used.

Discussion

Analysis revealed treatment with either study device paired with counseling (control and experimental) to have a statistically significant effect on the primary measure of TRQ scores and the secondary measure of awareness levels. This indicates that use of either the customized Neuromonics Oasis™ or COTS Apple iPod Touch™ with generic tinnitus apps used in tandem with counseling results in the reduction of both the amount of time one is aware of their tinnitus and the negative psychological effects tinnitus has on HRQoL. Similarly, Goddard, Berliner and Luxford (2009) concluded that the Neuromonics device provided significant reduction in the effects tinnitus has on HRQoL as measured with the TRQ ($p \sim .001$). A secondary control device was not utilized in that study; however, 32 percent of their study participants returned the issued Neuromonics device, with participants stating they found no subjective benefit with its use. Newman and Sandridge (2012) reported that use of either the NTTP/Neuromonics device or an ear level SG provided a statistically significant reduction ($p < .001$) in their participants' HRQoL as measured by the Tinnitus Handicap Inventory (THI). Newman and Sandridge (2012) concluded both study devices were viable options for the treatment of disturbing tinnitus, with one not superior to another. Use of SGs such as COTS portable music players (such as MP3 players or Apple iPod™ devices) when used in tandem with TRT have also shown to be clinically effective in the reduction of THI scores (Fukuda, Miyashita, Inamoto and Mori, 2010).

Analysis in the current study revealed for either device, differences between pre- and post-treatment scores of BBNMMLs were not statistically significant. However, differences on post-treatment BBNMML measures between groups were found to be statistically significant. Descriptive statistics revealed a lower post-treatment mean score for Neuromonics Oasis™ users than for those who used the Apple iPod Touch™ device. This indicates that after treatment with the Neuromonics Oasis™ device, lower levels of noise were needed to effectively mask the participant's tinnitus, suggesting the tinnitus to be less intrusive.

Disturbance levels were initially revealed to be significantly different in post-measure scores for pooled data of all study participants. Further analysis revealed that this was true only for participants in the Neuromonics Oasis™ group, who found the amount of tinnitus they were aware of to be significantly less disturbing at the conclusion of the study than at the onset. This was not so for participants who used one of the pre-loaded tinnitus treatment apps on the Apple iPod Touch™. Taking the findings of disturbance levels in combination with awareness levels, one can conclude that participants who used the Apple iPod Touch™ with generic tinnitus treatment apps in addition to TRT counseling saw a significant reduction in the amount of time they were aware of their tinnitus. However, the amount of time their tinnitus was considered disturbing was equivalent. The Neuromonics Oasis™ device users saw a reduction in both the percentage of time they were aware of their tinnitus and the amount of time said tinnitus was considered disturbing.

Analysis revealed the only main effect across participant groups present in the current study was ‘time’ as defined by pre- and post-study measurements. This would indicate that the treatment itself, despite the method or application used, provided a statistically significant difference in TRQ scores and awareness levels. A statistically significant difference as identified by a decrease in disturbance levels was only noted in those participants who used the Neuromonics Oasis^{TM} and NTTP treatment method.

Caution in generalizing and applying the findings from this study is warranted for several reasons. First, the sample size is relatively small, with only 35 participants in total (Neuromonics Oasis^{TM} n = 25, Apple iPod Touch^{TM} n = 10). The sample size for the LDL measures was even smaller, with only 25 participants (Neuromonics Oasis^{TM} n = 16, Apple iPod Touch^{TM} n = 9). Due to the smaller sample size of the group who used the Apple iPod Touch^{TM}, it is possible that a larger variability exists, which could allow data to fail to reach statistical significance, than was captured in the current study. As the participants in the control group were free to use one of the two provided tinnitus treatment apps, the efficacy of the apps relative to each other is unknown. A larger participant pool of listeners who use the COTS Apple iPod Touch^{TM} may allow for a more representative sample of disturbance levels at pre- and post-treatment time points.

Conclusion

Results indicate both treatment devices and associated counseling methods provide sufficient intervention to decrease awareness of and to alleviate the negative psychological symptoms that affect HRQoL associated with debilitating tinnitus. Use of the NTT protocol also provided a statistically significant reduction in disturbance levels which was not evidenced in the Apple iPod Touch^{TM} group. Additionally, the intensity (as measured in dB) needed to effectively mask the listener’s tinnitus was significantly and appreciably lower for Neuromonics Oasis^{TM} users compared to the Apple iPod Touch^{TM} users. These findings would suggest that both devices and counseling methods would provide sufficient treatment options for debilitating tinnitus. Further, results indicate use of the NTT protocol would provide more global reductions on secondary efficacy study measures than the treatment method utilized by that of the control group.

Recommendations

Results obtained from the TRQ, which was the primary measure of treatment efficacy in the current study, suggest that use of either treatment device provides statistically significant reduction in HRQoL. Further, patient needs and wants, in addition to the cost of treatment should be taken into consideration when making treatment recommendations. Continued research with both devices is encouraged at this time. First, a follow up study is proposed with larger, equal sample sizes to address current study limitations. The authors also suggest coupling pre- and post-treatment measures with imaging studies to aid in the identification of active brain structures. This could potentially be used to develop an objective measure of neuroplasticity in

the treatment of tinnitus. Further research is indicated to determine the long term effectiveness of these devices and associated counseling protocols.

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Appendix

Manufacturers List.

Apple
1 Infinite Loop
Cupertino, CA 95014

Bang & Olufsen
1751 Lake Cook Road, Suite 620
Deerfield, IL 60015

Explosive Apps
Tinnitus Masker for Apple iOS (Version 1.0)
Address not available

LoL Software
Tinnitus Relief Pro for Apple iOS (Version 1.0)
Address not available

Neuromonics
8774 Yates Drive
Westminster, CO 80031

Department of the Army
U.S. Army Aeromedical Research Laboratory
Fort Rucker, Alabama, 36362-0577
www.usaarl.army.mil

U.S. Army Medical Research and Materiel Command